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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/420,046	10/18/1999	HENRY C. LIN, M. D.		2270

7590 08/26/2002

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EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	21

DATE MAILED: 08/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/420,046	LIN, M. D., HENRY C.
	Examiner	Art Unit
	Susan Tran	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 13 June 2002.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 96-138 is/are pending in the application.

4a) Of the above claim(s) 131-136 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 96-130,137 and 138 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

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## **DETAILED ACTION**

Receipt is acknowledged of applicants Corrected Filing Receipt filed 12/26/01, Request for Extension of Time filed 12/26/01 and 04/30/02, Election 06/13/02, and Amendment C filed 06/13/02.

### ***Election/Restriction***

Applicant's election with traverse of specie (a) capsule, and group II, claims 114-130 invention in Paper No. 20, 06/13/02 is acknowledged. Applicants argues that inventions of Groups I and II are the same since, both recite "...absorption promoting...and/or gastric emptying slowing," is persuasive. Thus, inventions I and II are now subject to being rejoined.

Claims 131-136 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 20.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 96-130 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27-32, 38-41, 44-48, and 62 of U.S. Patent No. 5,977,175. Although the conflicting claims are not identical, they are not patentably distinct from each other because, they claimed the same subject matter, which is an “anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastric transit slowing and/or gastric emptying slowing” formulation.

***Claim Rejections - 35 U.S.C. § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 96, 98-106, 114, 116, 117, and 119-125 are rejected under 35 U.S.C. 102(b) as being anticipated by Pedersen et al. US 4,572,833.

Pedersen teaches controlled release composition comprising multiple-unit of active substance being coated with hydrophobic layer (abstract and column 3). The hydrophobic material can be selected from oils, waxes, fats, including higher fatty acids, and mixtures thereof (column 4). Active substance, dosage forms and coating agent are disclosed in columns 6-8.

***Claim Rejections - 35 U.S.C. § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 96, 98-106, 114, 116, 117, 119-125, 137, and 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pedersen et al.

Pedersen is relied upon for the reason stated above. In the case that the applicant can overcome the above 102(b) rejection, it is the examiner's position that it would have been *prima facie* obvious for one of ordinary skill in the art to modify Pedersen's multi-unit controlled release composition with the expectation of at least similar result, since Pedersen teaches the

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advantageous result in the use of hydrophobic material to control the release rate of active substance throughout the GI tract.

5. Claims 96, 114, and 118 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pedersen et al., and Crissinger et al. US 5,411,751.

Pedersen is relied upon for the reasons stated above. Pedersen does not teach the additional of nutrient agent as claimed in claim 118.

Crissinger teaches the use of (C<sub>16</sub>-C<sub>22</sub>) fatty acid in food product to reduce GI irritation (abstract). The food product further comprising vitamins and minerals (column 3). Thus, it would have been obvious for one of ordinary skill in the art to prepare Pedersen's composition using the fatty acid in view of the teaching of Crissinger, because the references teach the advantageous result in the use of fatty acid. The expected result would be controlled release dosage form useful in pharmaceutical and/or food products.

#### *Pertinent Arts*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Asher et al., Bechgaard et al., Thomas et al., and Rowe are cited as being of interest for the teachings of controlled release formulation.

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*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K PAGE  
SUPERVISORY PATENT EXAMINER  
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